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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/876,304	06/07/2001	Isiah M. Warner	9802.2 Warner	1549

25547 7590 03/26/2003

PATENT DEPARTMENT
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EXAMINER

AUDET, MAURY A

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 03/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/876,304

Applicant(s)

WARNER ET AL.

Examiner

Maury Audet

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-23 and 40-53 is/are pending in the application.
- 4a) Of the above claim(s) 40-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13, 18 and 45-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 18-23 and 40-53 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Change of Art Unit Designation

1. Please note: The Art Unit location of this application in the PTO has changed from Art Unit 1743 to Art Unit 1654. To aid in matching papers in this application, all further correspondence regarding this application should be directed to **Group Art Unit 1654**.

Preliminary Amendment

2. The Preliminary Amendment, filed June 7, 2001, Paper No. 3, is acknowledged.

Information Disclosure Statement

3. The Information Disclosure Statement filed January 10, 2002 has been considered. An initialed copy of Form PTO-1449 in accordance with MPEP § 609 is attached.

Election/Restrictions

4. Restriction to one of the following inventions is required under 35 U.S.C. 121. In accordance with 37 CFR 1.142, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. Claims 18-23, and 45-53, drawn to micelles, compositions, and compounds containing dipeptides, classified in class 514, subclass 2, class 424, subclass 1.69.
- II. Claims 40-44, drawn to micelles containing oligopeptides, classified in class 530, subclass 300+.

The inventions are distinct, each from the other because of the following reasons:

Invention I and II above are independent and distinct, each from the other. They have acquired a separate status in the art (i.e. classification) as a separate subject for inventive effect and require independent searches. The search for each of the above inventions is not co-

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extensive particularly with regard to the literature search. Further, a reference, which would anticipate the invention of one group, would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application. Restriction for examination purposes is therefore proper.

During a telephone conversation with John Runnels, Attorney for Applicant, on March 7, 2003, a provisional election was made with traverse to prosecute the invention of Group I, claims 18-23, and 45-53. Claims 40-44 were withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

As part of the response to this action, Applicant is asked to specifically cancel the non-elected claims.

Status of the Claims

5. Claims 18-23, and 40-53 were originally filed in the present application. The claims were subject to restriction, as discussed supra. Claims 40-44 are withdrawn from consideration. Claims 18-23, and 45-53 are pending and examined on the merits.

Rejections

35 U.S.C. § 112, 2nd ¶ Indefinite

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18-19 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 18-21 are drawn to a "a polymerized dipeptide chiral

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micelle; wherein the micelle is *not* a polymer of a compound selected from the group consisting of N-undec-10'-enoyl-L-prolyl-L-glutamic acid, N-undec-10'-enoyl-L-methionyl-L-glutamic acid, and n-undec-10'-enoyl-L-phenylalanyl- β -alanine (cl. 18); or wherein the micelle comprises a polymer of monomers, wherein each of said monomers comprises an unsaturated hydrocarbon chain linked to a chiral peptide (cl. 19); or wherein said micelle comprises a co-polymer of a plurality of different dipeptide chiral surfactant monomers (cl. 21)." Although claim 18 negatively recites 3 dipeptides known in the art, beyond this recitation, claim 18 and its dependant 19 and 21 fail to distinctly claim that which Applicant regards as his invention. Claim 19 does not point out which monomers form the polymers and where the hydrocarbons are to be linked on the chiral dipeptide (essentially undefined) of claim 18, and claim 22 does not distinctly claim what 'different' dipeptide monomers form the co-polymers of the micelles (namely, does the claim language mean a combination of the three negatively claimed dipeptides are to make up the co-polymers or a combination of *any* different dipeptides other than the negatively claimed dipeptides?). The only clarification of what is regarded as the invention is positively recited in claim 23 (8 conformations of four distinct dipeptides, which are also described in the specification). The specification does not clarify claims 18-19 and 21, and merely broadly refers to any dipeptide (other than the 3 negatively claimed in claim 1 and on specification page 6) as within the invention. Applicant is asked to amend the claims to distinctly claim: which polymers of compounds make up the dipeptide chiral micelles (cl. 18.); what monomers form the polymers and where the hydrocarbon chain is linked on the specific dipeptide of claim 18 (cl. 19); and what specific 'different' dipeptide monomers form the co-polymers of the micelles (cl.21).

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Claim 20 is further rejected Claim 20 under 112 2nd. Claim 20 is drawn to a "mixture of a plurality of different polymerized chiral micelles (containing dipeptides), wherein each of said polymerized chiral micelles is a micelle as recited in Claim 18." It is unclear as to whether the invention includes a mixture of the 'disclaimed' dipeptides in a mixture (i.e. the group consisting of N-undec-10'-enoyl-L-prolyl-L-glutamic acid, N-undec-10'-enoyl-L-methionyl-L-glutamic acid, and n-undec-10'-enoyl-L-phenylalanyl- β -alanine), or a mixture of any known polymer of a compound selected from the above 'disclaimed' dipeptides. It was not found in the specification where this is clearly described. Applicant is asked to clarify which of the two interpretations above is claimed, and also point to the specification where support for the claimed invention of claim 20 may be found.

35 U.S.C. § 112, 1st ¶, Written Description

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a "written description" rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Vas-Cath Inc. V. Mahurka, 19 USPQ2d 1111, states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the "written description" inquiry, is *whatever is now claimed*" (see page 1117).

The claimed invention, specific to claims 18-21, is drawn to a "a polymerized dipeptide chiral micelle; wherein the micelle is *not* a polymer of a compound selected from the group consisting of N-undec-10'-enoyl-L-prolyl-L-glutamic acid, N-undec-10'-enoyl-L-methionyl-L-glutamic acid, and n-undec-10'-enoyl-L-phenylalanyl- β -alanine (cl. 18); or wherein the micelle comprises a polymer of monomers, wherein each of said monomers comprises an unsaturated hydrocarbon chain linked to a chiral peptide (cl. 19); or wherein said micelle comprises a co-polymer of a plurality of different dipeptide chiral surfactant monomers (cl. 21)." The invention is also drawn to a "composition of matter comprising a mixture of a plurality of different polymerized chiral micelles, wherein each of said polymerized chiral micelles is a micelle as recited in claim 18" (cl. 20). As to claim 18-20, neither the claims, nor the specification has defined the specific compound polymers are to be micelles of the invention (outside the three listed) (cl. 18); what specific unsaturated hydrocarbon monomers may be linked to the micelle's peptides, and where on those peptides (cl. 19); what different dipeptide monomers are attached as a co-polymer (cl. 21); and what specific micelles are to be included in the composition mixture (cl. 20)?

One of skill in the art would not recognize from the disclosure that the Applicant was in possession of the micelle genus, namely what specific compound polymers (cl. 18), unsaturated hydrocarbon monomers (cl. 19), dipeptide monomers (cl. 21), and micelles (in composition) (cl.

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20) are contemplated to work in the invention. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (see *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

35 U.S.C. § 102 Anticipatory

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 18-19, 21-23 (to L-configured dipeptide polymers), 45 (as to L-configured dipeptide polymers), and 46, 48, 50, and 52 to dipeptide micelles are rejected under 35 U.S.C. 102(a) as being anticipated by Billiot et al. (April 1, 1998, *Anal. Chem.*, pp. 1375-1381, specifically p. 1376, 2nd ¶).

The claimed invention is drawn to a drawn to a "a polymerized (reversed (cl. 22)) dipeptide chiral micelle (comprising a polymer of 8 conformations (L- and D-) of four distinct dipeptides (cl. 23)); wherein the micelle is *not* a polymer of a compound selected from the group consisting of N-undec-10'-enoyl-L-prolyl-L-glutamic acid, N-undec-10'-enoyl-L-methionyl-L-glutamic acid, and n-undec-10'-enoyl-L-phenylalanyl- β -alanine (cl. 18); or wherein the micelle comprises a polymer of monomers, wherein each of said monomers comprises an unsaturated hydrocarbon chain linked to a chiral peptide (cl. 19); or wherein said micelle comprises a co-polymer of a plurality of different dipeptide chiral surfactant monomers (cl. 21)." The invention

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is further drawn to compounds of the 8 polymer conformations (L- and D-) of four distinct dipeptides of claim 23 (cl. 45-53).

Billiot et al. teach the 4 L-configuration dipeptide polymers and compounds (p. 1376, 2nd ¶). Billiot et al. also the micellar nature of enantiomeric chiral compounds (p. 1375, ¶1).

Thus, Billiot et al. teach the 4 polymerized dipeptide chiral micelle species of Applicant's cl. 18-20, 21-23 (as to the 4 L-configured polymers)). Although claim 20 was analyzed supra as indefinite under 112 2nd, for purposes of this outlined rejection, the claim has been interpreted as drawn to a mixture of the 4 dipeptide chiral micelles of Billiot et al.

35 U.S.C. § 103 Obviousness

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 23 and 45(as to D-configured dipeptide polymers), and claims 47, 49, 51, and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Billiot et al. in view of Daly et al.

The claimed invention is drawn to a drawn to a "a polymerized (reversed (cl. 22)) dipeptide chiral micelle (comprising a polymer of 8 conformations (L- and D-) of four distinct dipeptides (cl. 23)); wherein the micelle is *not* a polymer of a compound selected from the group consisting of N-undec-10'-enoyl-L-prolyl-L-glutamic acid, N-undec-10'-enoyl-L-methionyl-L-glutamic acid, and n-undec-10'-enoyl-L-phenylalanyl-β-alanine (cl. 18); or wherein the micelle comprises a polymer of monomers, wherein each of said monomers comprises an unsaturated hydrocarbon chain linked to a chiral peptide (cl. 19); or wherein said micelle comprises a co-

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polymer of a plurality of different dipeptide chiral surfactant monomers (cl. 21).” The invention is further drawn to compounds of the 8 polymer conformations (L- and D-) of four distinct dipeptides of claim 23 (cl. 45-53). Specifically, as applied here, the invention is drawn to the D-configuration of the 4 respective dipeptide polymers and compounds.

Billiot et al. teach, as discussed supra, the 4 polymerized dipeptide chiral micelle species of Applicant’s cl. 18-20, 21-23 (as to the 4 L-configured polymers). Billiot et al. also teach “further studies are planned with a *variety of other types of chiral analytes* and various other dipeptide surfactants” (p. 1381). Although Billiot et al. teaches that further studies, which may include D-configuration analysis are contemplated, Billiot et al. does not specifically teach the D-configuration of the polymers and compounds.

Daly et al. teach that “unless specified otherwise, the backbone of the polymer recited in each of the claims may comprise L-amino acid residues, or D -amino acid residues; but a given polymer backbone should not contain equivalent amounts of both L-amino acid residues and D -amino acid residues” (column 10, ¶ 3). Daly et al. teach, as Billiot et al. does in practice, namely wherein the 4 L-configured dipeptide polymers and compounds only having L-configurations (and Applicant in cl. 23, and 45-53); that as long as the D- and L-configurations are not mixed, alternative forms of the other are equivalently attainable.

One of ordinary skill in the art at the time the invention was made would have found it prima facie obvious to form the D-configured dipeptide polymers and compounds of the L-configured equivalents taught by Billiot et al., because Daly et al. teach that both are equivalently maintained, as long as the D- and L-configured peptides of the dipeptide polymer or compound are not intermixed, and Daly et al. is drawn to polymers and enantiomers in the same field of art.

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Conclusion

10. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 703-305-5039. The examiner can normally be reached from 7:00 AM – 5:30 PM, off Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached at 703-306-3220. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-1234 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

MA

March 21, 2003

Brenda Brumback
BRENDA BRUMBACK
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